

## REMARKS

### Amendments to the Claims

Claims 1-13, 15-43, 45-48, 50-58, 60-79, 84-88 and 91-96 were pending.

Claims 3-13, 15-33, 35, 52, 66-79 and 84-88 were withdrawn.

Claims 86 and 92 have been amended to correct obvious typographical spelling errors.

No new matter has been added. Entry of these amendments is respectfully requested.

### Election/Restriction Requirement

Applicants hereby traverse the Election/Restriction Requirement dated December 2, 2010 for at least the reasons set forth below.

In the previous Restriction Requirement dated August 9, 2005, the Examiner identified “growth factor” and “inhibitors of TNF-alpha synthesis” as patentably distinct and searchable species. However, the Examiner has now imposed a further election requirement for various individual “growth factors” and “inhibitors of TNF-alpha synthesis” in the current Election/Restriction Requirement dated December 2, 2010.

Pursuant to the Manual of Patent Examining Procedure (MPEP) § 803, “Restriction - When Proper” “If the search and examination of all the claims in an application can be made **without serious burden**, the examiner **must** examine them on the merits, **even though they include claims to independent or distinct inventions.**” *Id.* (emphasis added).

For Species Election #1, the Examiner requires election of a specific growth factor from the list of growth factors including six bone morphogenetic proteins (BMPs), OP-1, and TGF- $\beta$ . (*see* the Office Action at page 2). The search and examination regarding the previously elected species “growth factors” were already performed and the Examiner has issued several subsequent Office Actions on the merits. In fact, a claim directed specifically to a growth factor which is a “bone morphogenetic protein” was previously presented on April 4, 2006 as Claim 91, and the Examiner has examined that claim. Because the species set forth in the current Species Election #1 are fully embraced by the previously elected species of “growth factor” and because a claim directed specifically to “bone morphogenetic proteins” has been previously examined, the burden on the Examiner for examining claims directed to the individual “growth factors”

shown in Claims 91 and 92 would be, at most, minor and not serious. *See* MPEP § 904.03 (an examiner's search should, insofar as possible, cover all subject matter which the examiner reasonably anticipates might be incorporated into an applicant's amendment). Accordingly, pursuant to MPEP § 803, the Examiner should examine the pending claims on the merits without further imposing requirements for restriction or election.

For Species Election #2, the Examiner requires election of one antibody directed against TNF- $\alpha$  from a list of three monoclonal antibodies: adalimumab, CDP-571 and CDP-870 (*see* the Office Action at page 3). The search and examination regarding the previously elected species "inhibitors of TNF- $\alpha$  synthesis" were already performed and the Examiner has issued several Office Actions on the merits. In fact, a claim directed specifically to an inhibitor of TNF- $\alpha$  synthesis which is a "monoclonal antibody" was previously presented on April 4, 2006 as Claim 89. Because the species set forth in the current Species Election #2 are fully embraced by the previously elected species of "inhibitors of TNF-alpha synthesis" and because a claim directed specifically to a "monoclonal antibody" has been previously examined, the burden on the Examiner for examining claims directed to the individual "anti-TNF- $\alpha$  monoclonal antibodies" shown in Claims 93-95 should be, at most, minor and not serious. *See* MPEP § 904.03. Accordingly, pursuant to MPEP § 803, the Examiner has an obligation to examine the pending claims on the merits without further imposing requirements for restriction or election.


Applicants also note that Species Election Requirement #2 is in error because it improperly excludes infliximab. Pending independent Claim 96 is directed to a method of treating an inflamed orthopedic joint using "infliximab", and "infliximab" is a monoclonal antibody directed against TNF- $\alpha$ , fully encompassed by the scope of the previously elected species. Yet, "infliximab" was not included as a species in Species Election #2 in the Office Action ("antibodies directed against TNF- $\alpha$ "). As noted above, Applicants provisionally elect, with traverse, "infliximab" as the species for examination.

Applicants respectfully request that the Species Election Requirement # 1 of December 2, 2010 regarding "growth factors" be withdrawn for at least the reasons set forth above. In the alternative, Applicants respectfully request that the BMPs listed in the Requirement be reconsidered and examined as one species, because they were previously included as claimed

subject matter which has been examined. Applicants also respectfully request that Species Election Requirement #2 of December 2, 2010 regarding "antibodies directed against TNF- $\alpha$ " be withdrawn for at least the reasons stated above and that the three enumerated monoclonal antibodies be examined together with the infliximab monoclonal anti-TNF- $\alpha$  antibody.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By   
Hak J. Chang  
Registration No. 56,319  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: 2/02/11